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SHUMAKER & SIEFFERT, P. A.
1625 RADIO DRIVE
SUITE 300
WOODBURY, MN 55125

EXAMINER	
ALTER, ALYSSA M	

ART UNIT	PAPER NUMBER
3762	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/730,877	JANZIG ET AL.	
	Examiner	Art Unit	
	Alyssa M. Alter	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,17-32,34 and 35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,17-32,34 and 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/18/06 & 1/30/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-35 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. Claims 21 and 31 stand rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, the claiming of structures being in contact with or implanted within the body amounts to an inferential recitation of the body, which renders these claims non-statutory. The examiner recommends changing claims 21 and 31, "deliver stimulation to a brain of a patient" to --is adapted to deliver stimulation to the brain of a patient--.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 2, 6, 21, 23 and 31 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and

appear to be method claims since it provides no further structure, but a mere recitation of intended use for such structure.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-2, 8-10, 15-16, 18-21, 32-33 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Weinberg (US 5,674,260). Weinberg discloses an "electronics package 30 is a hybrid circuit structure containing various integrated circuits which are vertically stacked at different positions to create a multi-level circuit structure"(col. 3, lines 15-18).

As to claim 1, figure 3 displays "a group of integrated circuits 34, which may be random access memory (RAM) chips, mounted atop a platform 36. Underneath the platform 36 are additional electronic components (not shown) which are mounted to a substrate 38 and which communicate with the integrated circuits 34. An additional integrated circuit 40 is mounted directly to the substrate 38 and is not covered by the

platform 36"(col. 3, lines 19-26). The examiner considers the substrate 38 and the platform 36 to be a circuit board.

Since the integrated circuits 34 are mounted on a platform, which the examiner considers to be part of the circuit board, compared to integrated circuit 40, they are in a non-linear profile.

Since Weinberg discloses on col. 3, lines 21-24, "underneath the platform 36 are additional electronic components (not shown) which are mounted to a substrate 38 and which communicate with the integrated circuits 34". The examiner considers the additional electrical components 72, as depicted in figure 6, to be discrete components since Weinberg has discloses the additional components communicate with the integrated circuits and thus are not integrated circuits themselves.

As to claim 2, the functional language and introductory statement of intended use of claim 2 have been carefully considered but are not considered to impart any further structural limitations over the prior art. Since Weinberg utilizes a first and second surface of a circuit board as claimed by the Applicant, Weinberg is therefore capable of being implanted with the first surface away from the cranium and the second surface towards the cranium. In addition nothing prevents Weinberg from modifying the orientation of implantation. Therefore, the implantable medical device is capable of being implanted with the first surface away from the cranium and the second surface towards the cranium.

As to claim 8, the housing that houses the circuit board is also at a non-linear profile

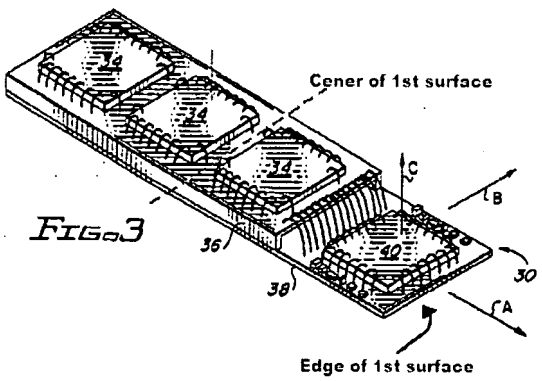
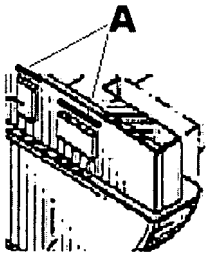


FIG. 3

as seen in figure 3, 4A and 4B, as the contoured lid 32.

As to claim 9, the height of the integrated circuits increase from an edge towards the center. A replication of figure 3 is included and displays the integrated circuit 40 on the edge of the first surface is at a smaller height than the integrated circuit 34 towards the center of the first surface.

As to claim 10, in the indicated portion of figure 6 at right, the discrete components 72, are further magnified. The highlighted portion indicates the two heights of components 72. Labeled as "A", the heights decrease from the edge of the second surface of the circuit board towards the center of the circuit board.



As to claims 15-16, 18, 32-33 and 35, figure 5 displays "the resistor board 68 in turn communicates with an electronics package (not shown) via wires 70"(col. 4, lines 24-26). Therefore, it follows that there is a feedthrough located in the electronic package 30 to enable wire connection to the resistor board via wires 70.

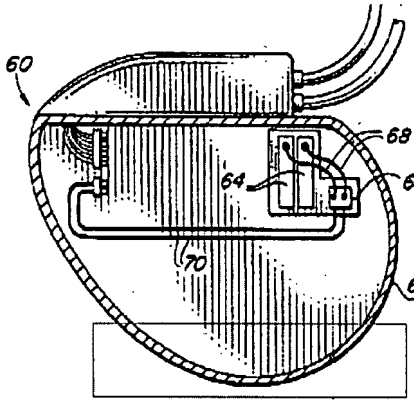


FIG. 5

Furthermore, as seen in the replication of figure 5 depicted above, the box placed around a portion of the implantable medical device indicates a "major surface of the housing" that is at a "non-parallel, non-perpendicular angle" from the feedthrough.

As to claim 19, the battery 74 is depicted in figure 6.

As to claims 20-21, the functional language and introductory statement of intended use of claims 20-21 have been carefully considered but are not considered to impart any further structural limitations over the prior art. Since Weinberg utilizes an implantable stimulation device as claimed by the Applicant, Weinberg is therefore capable of being used as an implantable neurostimulator to stimulate the brain. In addition nothing prevents Weinberg from utilizing the implantable stimulation device to function as a neurostimulator and stimulate the brain. Therefore, the implantable stimulation device is capable of being utilized as an implantable neurostimulation device to stimulate the brain.

2. Claims 22-23, 25-26 and 28-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Engmark et al. (US Patent Publication 20040082977 A1). Engmark et al. discloses a implantable medical device with an antenna coil 32, "electrical circuitry 22 typically contains numerous interconnected electrical components 23 mounted on circuit board 27 so as to form electrical module 28"(page 2, paragraph 21).

As to claim 22, the claim does not set forth the orientation at which the telemetry coil is substantially uneclipsed by the circuit board. Therefore, as depicted in figure 8, from the top view of the implantable system, the telemetry coil 32 is located in the second plane and is substantially uneclipsed by the circuit board 27 located in the first plane, wherein the two planes are parallel to each other, thus resulting in no eclipse.

As to claim 23, the functional language and introductory statement of intended use of claim 23 have been carefully considered but are not considered to impart any further structural limitations over the prior art. Since Engmark et al. utilizes a first and

second surface of a circuit board as claimed by the Applicant, Engmark et al. is therefore capable of being implanted with the first surface away from the cranium and the second surface towards the cranium. In addition nothing prevents Engmark et al. from modifying the orientation of implantation. Therefore, the implantable medical device is capable of being implanted with the first surface away from the cranium and the second surface towards the cranium.

As to claims 25-26, as previously mentioned, the electrical components 23 are mounted on circuit board 27 to form the electrical module 28. The examiner considers the electrical components to be the integrated circuits and discrete components.

Furthermore, figure 8 depicts the thickness of the circuit board and components and housing. Engmark et al. discloses on page 4, paragraph 39, "It will be noted in FIG. 8 that antenna coil 32 is spaced apart from housing 11 by distances 60, 61 and from substrate 27 by distance 62. It is desirable that distance 60 between a principal plane of coil 32 and a principal plane of housing 11 and distance 62 between a principal plane of coil 32 and a principal plane module substrate 27 be usefully approximately 0.5 mm or larger, conveniently approximately 0.7 mm or larger, and preferably approximately 0.76 mm or larger. The efficiency of antenna coil 32 degrades as the plane of coil 32 approaches closer to the plane of conductive housing 11 and/or the conductive portions of module substrate 27. The distances between the corners of coil 32 and housing 11, e.g., distance 61, is less important and can be smaller than distances 60, 62".

As to claim 28, Engmark et al. teaches on page 1, paragraph 4, the use of "a circuit board or flexible tape".

As to claim 29, the battery 20 is depicted in figure 7.

As to claim 30, Engmark et al. discloses "implantable medical devices such as pacemakers, defibrillators, neuro-stimulators, and the like"(page 1, paragraph 2).

As to claims 30-31, the functional language and introductory statement of intended use of claims 30-31 have been carefully considered but are not considered to impart any further structural limitations over the prior art. Since Engmark et al. utilizes an implantable medical device as claimed by the Applicant, Engmark et al. is therefore capable of being used as an implantable neurostimulator to stimulate the brain. In addition nothing prevents Engmark et al. from utilizing the implantable medical device to function as a neurostimulator and stimulate the brain. Therefore, the implantable medical device is capable of being utilized as an implantable neurostimulation device to stimulate the brain.

As to claims 32-35, "Circuit board 27 of module 28 includes metal contact areas 29 that are conveniently electrically coupled to inner portions 17 of one or more electrical feed-throughs 16 of device 10"(page 2, paragraph 21). "One or more feed-through connectors permit electrical communication to and from the electrical components and circuitry contained within the housing while at the same time maintaining the hermeticity of the device"(page 1, paragraph 3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

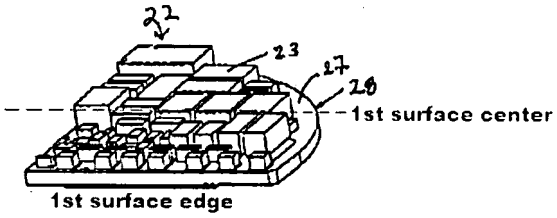
the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1-6 and 9-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engmark et al. (US Patent Publication 20040082977 A1) in view of Chen et al. (US 5,954,751). Engmark et al. discloses an implantable medical device with an antenna coil 32, "electrical circuitry 22 typically contains numerous interconnected electrical components 23 mounted on circuit board 27 so as to form electrical module 28"(page 2, paragraph 21). Engmark et al. discloses the claimed invention except for the integrated circuits on a first surface and discrete components on a second surface. Chen et al. teaches that it is known in the art to place a number of electronic device on one or both sides of a flat insulating substrate as set forth in column 1-2, lines 65-67 and 1-18, for the purpose of reducing the size of the implantable device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the electronic components as taught by Engmark et al. with the placement of electronic components on both sides of the circuit board or substrate as taught by Chen et al., in order to reduce the size of the implant and modify the implant to meet specific patient needs.

As to claims 2 and 6, the functional language and introductory statement of intended use of claims 2 and 6 have been carefully considered but are not considered to impart any further structural limitations over the prior art. Since Engmark et al. utilizes a first and second surface or plane of a circuit board as claimed by the Applicant, Engmark et al. is therefore capable of being implanted with the first surface or plane away from the cranium and the second surface or plane towards the cranium. In addition nothing prevents Engmark et al. from modifying the orientation of implantation. Therefore, the implantable medical device is capable of being implanted with the first surface or plane away from the cranium and the second surface or plane towards the cranium.

As to claim 9, the height of the integrated circuits increase from an edge towards the center. A replication of a portion of figure 7 is included and displays the integrated circuit on the edge of the first surface is at a smaller height than the integrated circuit towards the center of the first surface.



As to claim 10, the modified Engmark et al. discloses the claimed invention except for increasing height of discrete components on the second surface. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have adjusted the components by decreasing height, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse, 86 USPQ 70* (see MPEP 2144.04) Furthermore, a modification to the location of the

electronic components would enable a more streamline device that would be less noticeable under the patient's skin.

As to claims 11-12, as previously mentioned, the electrical components 23 are mounted on circuit board 27 to form the electrical module 28. The examiner considers the electrical components to be the integrated circuits and discrete components.

Furthermore, figure 8 depicts the thickness of the circuit board and components and housing. Engmark et al. discloses on page 4, paragraph 39, "It will be noted in FIG. 8 that antenna coil 32 is spaced apart from housing 11 by distances 60, 61 and from substrate 27 by distance 62. It is desirable that distance 60 between a principal plane of coil 32 and a principal plane of housing 11 and distance 62 between a principal plane of coil 32 and a principal plane module substrate 27 be usefully approximately 0.5 mm or larger, conveniently approximately 0.7 mm or larger, and preferably approximately 0.76 mm or larger. The efficiency of antenna coil 32 degrades as the plane of coil 32 approaches closer to the plane of conductive housing 11 and/or the conductive portions of module substrate 27. The distances between the corners of coil 32 and housing 11, e.g., distance 61, is less important and can be smaller than distances 60, 62".

As to claim 14, Engmark et al. teaches on page 1, paragraph 4, the use of "a circuit board or flexible tape".

As to claims 15-18, "Circuit board 27 of module 28 includes metal contact areas 29 that are conveniently electrically coupled to inner portions 17 of one or more electrical feed-throughs 16 of device 10"(page 2, paragraph 21). "One or more feed-through connectors permit electrical communication to and from the electrical

components and circuitry contained within the housing while at the same time maintaining the hermeticity of the device"(page 1, paragraph 3). Due to the curved edge of the housing, as seen in figure 7, the feedthrough is located at a non-parallel, non-perpendicular angle relative to a major surface of the housing. The examiner considers non-parallel, non-perpendicular to be at an angle other than 0, 90 or 180 degrees.

As to claim 19, the battery 20 is depicted in figure 7.

As to claim 20, Engmark et al. discloses "implantable medical devices such as pacemakers, defibrillators, neuro-stimulators, and the like"(page 1, paragraph 2).

As to claims 20-21, the functional language and introductory statement of intended use of claims 20-21 have been carefully considered but are not considered to impart any further structural limitations over the prior art. Since Engmark et al. utilizes an implantable medical device as claimed by the Applicant, Engmark et al. is therefore capable of being used as an implantable neurostimulator to stimulate the brain. In addition nothing prevents Engmark et al. from utilizing the implantable medical device to function as a neurostimulator and stimulate the brain. Therefore, the implantable medical device is capable of being utilized as an implantable neurostimulation device to stimulate the brain.

2. Claims 7 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Engmark et al. (US Patent Publication 20040082977 A1) or the modified Engmark et al. (US Patent Publication 20040082977 A1) as applied to claims 1-6 and 9-21, in view of Laird et al. (US 6,445,956 B1). Engmark et al. or the modified Engmark et al. discloses the claimed invention except for the tapered portion. Laird et al. teaches in

col. 1, lines 35-52, that a modification to an implantable medical device shape would reduce ischemia and necrosis. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the shape as taught by Engmark et al. with the tapered shape as taught by Laird et al., in order to minimize the risk of ischemia and necrosis.

Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the shape of implantable medical device, since it has been held that the configuration of the claimed element is a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed element was significant. *In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)* See the MPEP 2144.04.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GEORGE R. EVANISKO
PRIMARY EXAMINER
3/12/7

Alyssa M Alter
Examiner
Art Unit 3762